Remarks

Claims 1-26 and 42-55 are pending. A complete listing of the claims with status identifiers is attached hereto.

I. Priority

Contrary to the Examiner's erroneous allegation, the so-called "dual layer substrate" clearly is taught in the parent application, 09/022,322, filed February 11, 1998, now U.S. Patent No. 6,123,861. The Examiner's attention is directed to Col. 4, Lines 10-16 of the patent ("...bonding or attaching additional substrate wafers or other substrate materials..."). Applicants are therefore entitled to a priority date of at least February 11, 1998. The grandparent case, U.S. Patent No. 5,797,898 to Santini Jr., et al. (hereinafter "Santini") issued August 25, 1998. Accordingly, Santini cannot properly be considered as a "modifying reference under 35 U.S.C. §103(a) with priority under 35 U.S.C. § 102(b)."

II. Rejection Under 35 U.S.C. § 102

Claims 1-12, 15-25, 42, 43, 46, 48, 50, and 52-55 were rejected under 35 U.S.C. 102(b) as anticipated by DE 197 16 683 C1 to Roth et al. (hereinafter "Roth"). The rejection is respectfully traversed.

Roth was published June 4, 1998 (page 1 of translation). As discussed above, the present application has priority to at least February 11, 1998. Accordingly, Roth cannot be a prior art reference under 35 U.S.C. 102(b). The rejection thus is improper and should be withdrawn.

III. Rejection Under 35 U.S.C. § 103

Claims 13, 14, 26, 44, 45, 47, 49, and 50 were rejected under 35 U.S.C. § 103(a) as obvious over Roth in view of U.S. Patent No. 5,797,898 to Santini. The rejection is respectfully traversed.

As discussed above neither Roth nor Santini can be considered a prior art reference under 35 U.S.C. § 102(b). The rejection thus is improper and should be withdrawn.

IV. Double Patenting

Claims 1-26, 42-44, 46, 48, 50, and 52-55 were rejected under the doctrine of obviousness-type double patenting in view of claims 1-29 of Santini in view of Roth. The rejection is respectfully traversed.

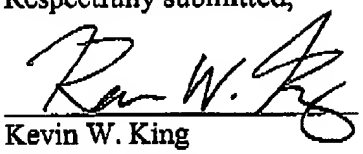
The rejection does not comply with M.P.E.P. § 804, which states that

> "[a]ny obviousness-type double patenting rejection should make clear:
> (A) The differences between the inventions defined by the conflicting claims...; and
> (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent."

The Office Action improperly relies on Roth. No proper evidence or reasoned argument has been provided why one skilled in the art would consider the differences **in the claims** to be obvious variants. Accordingly, no *prima facie* case of obviousness-type double patenting has been made. The rejection should therefore be withdrawn.

For these reasons, applicants respectfully request allowance of claims 1-26 and 42-55.

Respectfully submitted,



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Complete Listing of Claims

1. (Previously amended) A microchip device for the release of molecules comprising:

a substrate comprised of two or more substrate portions bonded together;

at least two reservoirs in the substrate, each containing molecules for release; and

a reservoir cap positioned on, or within a portion of, each of said at least two reservoirs and over the molecules for release, the molecules for release being releasable from the device by diffusion through or upon disintegration of the reservoir caps, wherein the release of the molecules from each reservoir is controlled by said diffusion through or disintegration of the reservoir cap positioned thereover.

2. (Original) The device of claim 1 wherein the substrate comprises an upper substrate portion adjacent the reservoir cap and a lower substrate portion distal the reservoir cap.

3. (Original) The device of claim 2 wherein a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion, the two reservoir sections forming a single reservoir.

4. (Original) The device of claim 3 wherein the reservoir section in the lower substrate portion has a volume that greater than the reservoir section in the upper substrate portion.

5. (Original) The device of claim 2 wherein the lower substrate portion is provided with an internal reservoir cap interposed between a reservoir section of the upper substrate portion and a reservoir section of the lower substrate portion, wherein release of the molecules from the reservoir section in the lower substrate portion is controlled by diffusion through or disintegration of the internal reservoir cap.

6. (Original) The device of claim 5 wherein the internal reservoir cap is disintegratable, so that the two reservoir sections form a single reservoir.

7. (Original) The device of claim 5 wherein the reservoir section of the lower substrate portion contains molecules different in quantity, type, or both quantity and type, from the molecules contained in the reservoir section of the upper substrate portion.

8. (Previously amended) The device of claim 1, wherein one of said at least two reservoirs comprises different types of molecules, different amounts of molecules, or combinations thereof, compared to another of said at least two reservoirs.

9. (Original) The device of claim 1 wherein release of the molecules is controlled by a release system incorporating the molecules in the reservoir.

10. (Original) The device of claim 9 wherein at least one reservoir cap is disintegratable and the release system in a reservoir is disintegratable to release the molecules after the disintegration of the reservoir cap.

11. (Previously amended) The device of claim 1, further comprising a cathode, a microprocessor, a timer, a demultiplexer, and a power source, wherein at least one reservoir cap is an anode, such that upon application of an electric potential between the cathode and anode, said at least one reservoir cap disintegrates to release the molecules from the reservoir which is under said at least one reservoir cap.

12. (Original) The device of claim 9 wherein the release system comprises drug molecules in an excipient or diluent.

13. (Original) The device of claim 9 wherein the release system further comprises a biodegradable matrix.

14. (Original) The device of claim 1 wherein at least one reservoir cap is non-disintegratable and wherein the rate of diffusion of the molecules through the cap determines the time at which the molecules are released from the reservoirs.

15. (Original) The device of claim 1 wherein the substrate comprise three or more substrate portions bonded together.

16. (Previously amended) A method for the delivery of molecules comprising:

providing at a site where molecules are to be delivered a microchip device which comprises a substrate comprised of two or more substrate portions bonded together, at least two reservoirs in the substrate, each containing molecules for release, and a reservoir cap positioned on, or within a portion of, each of said at least two reservoirs and over the molecules for release; and

controllably releasing said molecules from each of the reservoirs by said diffusion through or disintegration of each of the reservoir caps.

17. (Previously amended) The method of claim 16, wherein the molecules for release comprise a drug and the device is provided at the site by implanting or injecting the microchip into a patient.

18. (Previously amended) The method of claim 17, wherein the drug is selected from the group consisting of nucleic acids, proteins, amino acids, polysaccharides, organic molecules, and synthetic molecules.

19. (Previously amended) The method of claim 17, wherein the drug is in combination with a pharmaceutically acceptable carrier.

20. (Previously amended) The method of claim 16, wherein the molecules for release comprise a diagnostic reagent or a chemical reagent.

21. (Original) The method of claim 16 wherein the molecules are released in a pulsatile or continuous manner.

22. (Original) The method of claim 16 wherein controlling the release of the molecules is performed using a release system incorporating the molecules in the reservoir.

23. (Original) The method of claim 22 wherein the release system is formed by the molecules to be released.

24. (Original) The method of claim 23 wherein at least one reservoir cap is disintegratable and the reservoir caps are positioned on the reservoirs over the release system, wherein the rate of disintegration of the reservoir cap or the rate of diffusion of the molecule through the reservoir cap determines the time at which the molecules are released from the reservoir.

25. (Previously amended) The method of claim 16, wherein the device further comprises a cathode, a microprocessor, a timer, a demultiplexer, and a power source, wherein at least one reservoir cap is an anode, and wherein the method further comprises applying an electric potential between the cathode and anode, to release the molecules from the reservoir under said at least one reservoir cap.

26. (Original) The method of claim 16 wherein at least one reservoir cap is non-disintegratable and wherein the rate of diffusion of the molecules through the cap determines the time at which the molecules are released from the reservoirs.

27-41. (Canceled).

42. (Previously added) The device of claim 1, wherein the molecules for release comprise drug molecules.

43. (Previously added) The device of claim 42, wherein the drug molecules are in combination with a pharmaceutically acceptable carrier.

44. (Previously added) The device of claim 42, wherein the drug molecules comprise a nucleic acid, a protein, an amino acid, or a polysaccharide.

45. (Previously added) The device of claim 42, wherein the drug molecules comprise a hormone.

46. (Previously added) The device of claim 42, wherein the drug molecules comprise a synthetic, organic molecule.

47. (Previously added) The device of claim 42, wherein the drug molecules are selected from the group consisting of anesthetics, vaccines, chemotherapeutic agents, metabolites, immunomodulators, antioxidants, antibiotics, and ionic channel regulators.

48. (Previously added) The device of claim 1, wherein the molecules for release comprise a diagnostic reagent or a chemical reagent.

49. (Previously added) The device of claim 48, wherein the molecules comprise a chemical reagent for use in a polymerase chain reaction or another nucleic acid amplification procedure.

50. (Previously added) The device of claim 1, wherein the molecules for release are in a liquid form.

51. (Previously added) The device of claim 1, wherein the molecules for release are in a solid form.

52. (Previously added) The device of claim 1, which releases the molecules in a pulsatile manner.

53. (Previously added) The device of claim 1, which releases the molecules in a continuous manner.

54. (Previously added) The device of claim 1, wherein the reservoir cap comprises one or more polymers.

55. (Previously added) The device of claim 1, wherein the reservoir cap comprises a metal thin film.